

August 29, 2014

The Honorable Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1612-P, Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Sent via email to: <http://www.regulations.gov>

Re: Medicare Program; Revision to Payment Policies under the Physician Fee Schedule, Section III. I.  
Reports of Payments or Other Transfers of Value to Covered Recipients

Dear Administrator Tavenner:

The American Nurses Association (ANA<sup>®</sup>) and American Nurses Credentialing Center (ANCC<sup>®</sup>) appreciate the opportunity to comment on the proposed changes to the Open Payments Program. ANA and ANCC support the aim of increasing transparency to ensure integrity in continuing education of healthcare professionals but remain concerned about the method for determining when payments are exempt from reporting under 42 USC 403.904(g)(1).

ANCC is a global leader in the field of healthcare accreditation. The Accreditation Program of ANCC, a subsidiary of ANA, identifies organizations worldwide that demonstrate excellence in continuing nursing education (CNE). Accredited organizations use evidenced-based ANCC criteria to plan, implement and evaluate high quality CNE activities. As a result, governmental agencies, national health ministries, nursing organizations, healthcare employers, and continuing education enterprises rely on ANCC accreditation to advance professional nursing practice and improve patient and system outcomes. Additionally, ANCC partnered with the Accreditation Council for Continuing Medical Education (ACCME<sup>®</sup>) and the Accreditation Council for Pharmacy Education (ACPE<sup>®</sup>) to establish the first and only innovation in the world offering three accreditations in one review process. Joint Accreditation for Interprofessional Continuing Education™ (Joint Accreditation Program) promotes interprofessional education (IPE) activities specifically designed to improve interprofessional collaborative practice (IPCP) in health care delivery.

As explained in detail in the February 5, 2014 letter appended hereto and incorporated herein by reference, the ANCC Accreditation Program's Content Integrity Standards (ANCC CIS) ensure that continuing nursing education is free from commercial influence. ANCC's Content Integrity Standards are equivalent to the ACCME Standards for Commercial Support (ACCME SCS), which are used by the Joint Accreditation Program to ensure integrity in IPE.



ANA and ANCC are deeply concerned that CMS proposes to eliminate 42 CFR 403.904(g)(1). ANA and ANCC urge CMS to amend §403.904(g)(1) as follows:

**§ 403.904 Reports of payments or other transfers of value to covered recipients.**

\* \* \*

(g) Special rules for payments or other transfers of value related to continuing education programs.

(1) Payments or other transfers of value provided as compensation for speaking at a continuing education program are not required to be reported, if all of the following conditions are met:

(i) The event at which the covered recipient is speaking **has been provided by an organization that meets accreditation or certification requirements as verified by the Joint Accreditors of Interprofessional Healthcare Continuing Education to satisfy industry standards for integrity and commercial support.** ~~meets the accreditation or certification requirements and standards for continuing education of one of the following:~~

~~(A) The Accreditation Council for Continuing Medical Education.~~

~~(B) The American Academy of Family Physicians.~~

~~(C) The American Dental Association's Continuing Education Recognition Program.~~

~~(D) The American Medical Association.~~

~~(E) The American Osteopathic Association.~~

(ii) The applicable manufacturer does not pay the covered recipient speaker directly.

(iii) The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

(2) Payments or other transfers of value that do not meet ~~all~~ of the requirements in paragraph (g)(1) must be reported as required by this section.

(i) Payments or other transfers of value that meet the requirements in paragraph (g)(1)(i) of this section, but not also (g)(1)(ii) or (g)(1)(iii) of this section or both, must be reported under the nature of payment category "Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program."

(ii) Payments or other transfers of value that do not meet the requirements in paragraph (g)(1)(i) of this section should be reported under the nature of payment category "Compensation for serving as a faculty or as a speaker for a unaccredited and non-certified continuing education program."

(iii) Payments or other transfers of value for speaking engagements not related to ~~medical~~ **healthcare professional** education should be reported under the nature of payment category "Compensation for services other than consulting, including serving as a speaker at an event other than a continuing education program."

This revision meets the important intent of distinguishing accredited, certified education from promotional education. This recommendation is consistent with the goals of CMS to eliminate the list of healthcare accreditors currently found at § 403.904(g)(i)(A)-(E) and broaden the exemption, without requiring CMS to vet educational providers or establish its own standards. This recommendation also is consistent with the approach recommended by ACCME in its August 21, 2014 letter to you.

The Joint Accreditors (ACCME, ANCC and ACPE) are uniquely equipped to undertake the verification process. ANA and ANCC envision that the process would be public, open and transparent and would ensure compliance with evidence-based, industry standard practices for commercial support to sustain a qualified health professional workforce to improve patient outcomes.

Sincerely,



Debbie Hatmaker, PhD, RN, FAAN  
ANA Executive Director



Linda Lewis, MSA, RN, NEA-BC, FACHE  
EVP and Chief ANCC Officer

# APPENDIX





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February 5, 2014

Marilyn B. Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
The United States Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: *Request to Add American Nurses Credentialing Center to List of Accreditors  
Section 904(g)(1)(i-iii) of 42 CFR Parts 402 and 403 ; Medicare, Medicaid, Children's Health Insurance  
Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests Final Rule*

Dear Administrator Tavenner:

The American Nurses Association ("ANA") appreciates the opportunity to follow up on our discussion related to the implications of § 6002 of the Affordable Care Act. ANA, in conjunction with the American Nurses Credentialing Center ("ANCC"), hereby respectfully request that the Final Rule implementing the Physician Payments Sunshine Act (42 CFR Parts 402 and 403) be amended at Section 904(g) to clarify that payments or other transfers of value provided as compensation for speaking at a continuing education program that is provided or approved by an ANCC-accredited organization are not required to be reported under this Final Rule. This request reflects a need to ensure parity of treatment across the health professions.

ANA and ANCC applaud CMS for implementing strategies to improve transparency and ensure that educational activities are planned, implemented and evaluated independently from the influence of commercial interest organizations. Unfortunately, however, the Final Rule has created unintended barriers for accredited providers of Continuing Nursing Education ("CE"), including:

- Loss of physician colleagues to act as planners, faculty, speakers and reviewers for CE activities;
- Loss of funding from commercial interest organizations for CE activities; and
- Loss of support for interprofessional continuing education activities planned collaboratively with the goal of improving interprofessional collaborative practice in the clinical setting (an initiative strongly promoted by the Institute of Medicine to improve quality and safety).

To ensure a competent nursing workforce, registered nurses must meet professional development needs, including licensure and/or certification requirements, through participation in CE activities. The Physician Payment Sunshine Act ("Act"), and the confusion surrounding its implementation, have interfered with the ability of registered nurses to meet these needs. The barriers created by the Final Rule are unnecessary. ANCC Accreditation already meets the highest standards necessary to maintain independence from industry influence and ensure the integrity of CE activities.

The Response to Comments regarding the Final Rule acknowledges that: "Accredited and certified continuing education that complies with applicable standards of the accrediting and certifying entities generally includes safeguards designed to reduce industry influence" and, therefore, "payments or transfers of value made to support accredited and certified continuing medical education should remain in a distinct category from



unaccredited or non-certified continuing education.”<sup>1</sup> Unfortunately, the Final Rule failed to fully appreciate that physicians often participate in accredited continuing nursing education - as distinct from continuing medical education – and in activities that are either planned collaboratively by accredited organizations or planned by those that are jointly accredited by ANCC, the Accreditation Council for Continuing Medical Education (“ACCME”) and the Accreditation Council for Pharmacy Education (“ACPE”). As a result, there is a lack of clarity within the continuing healthcare education industry about whether payments to physicians participating in ANCC-accredited or jointly accredited continuing nursing education programs are excluded from the reporting requirement.<sup>2</sup> This lack of clarity has a deleterious impact on nurses’ ability to get the continuing education they need for continued licensure and/or certification and, ultimately, restricts their ability to practice.<sup>3</sup>

The *ANCC Content Integrity Standards for Industry Support in Continuing Nursing Educational Activities* are equivalent to those recognized for exclusionary purposes by CMS in the Final Rule. ANA and ANCC have been leaders in the move to ensure the integrity of nursing professional development since the Accreditation Program’s inception.

In 1972, ANA established a Commission on Continuing Education and, in 1974, published Standards for Continuing Education in Nursing. A formal accreditation system for continuing nursing education (CNE) was launched in 1975 following development of the standards. In 1991, the American Nurses Credentialing Center (ANCC) was created as a subsidiary of ANA, and the work of credentialing was transferred to ANCC. The ANCC Accreditation Program continues to develop and implement criteria for organizations that provide CE activities or approve other organizations or individuals that provide such activities. The ANCC Accreditation Program Standards contain operational requirements which are expressly designed for the purpose of ensuring content integrity in CE activities, including ensuring the planning process and all content is separated from the influence of any commercial interest organization. These standards were independently developed, maintained and monitored by the ANCC Accreditation Program until the formal ACCME Standards of Commercial Support were published in 2004.

In 2004, ACCME published its Standards for Commercial Support. When ANCC revised its accreditation program standards for its 2006 Manual, ANCC adapted the ACCME Standards for Commercial Support with permission from ACCME.

In 2008, ANCC, ACCME and ACPE collaborated to develop accreditation criteria for the Joint Accreditation Program, which accredits continuing education providers offering interprofessional activities that award contact hours for continuing medical, nursing and pharmacy education. The three organizations agreed to

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<sup>1</sup> 78 FR 9480, downloadable at <https://www.federalregister.gov/articles/2013/02/08/2013-02572/medicare-medicaid-childrens-health-insurance-programs-transparency-reports-and-reporting-of#p-213>

<sup>2</sup> Specifically, 42 CFR 403.904(g), Special rules for payments or other transfers of value related to continuing education programs, states: “(1) Payments or other transfers of value provided as compensation for speaking at a continuing education program are not required to be reported, if . . . : (i) [t]he event at which the [physician] is speaking meets the accreditation or certification requirements and standards for continuing education of one of the following: (A) The Accreditation Council for Continuing Medical Education[;] (B) The American Academy of Family Physicians[;] (C) The American Dental Association’s Continuing Education Recognition Program[;] (D) The American Medical Association[;] (E) The American Osteopathic Association.” Other conditions also apply and are satisfied by compliance with ANCC’s Accreditation Program criteria, including its Content Integrity Standards.

<sup>3</sup> The ANCC Accreditation Program Director has fielded numerous questions and concerns about the applicability of the Physician Payment Sunshine Act to accredited CNE activities. These questions and comments revealed that some physicians who are faculty for ANCC-accredited providers of continuing nursing education are refusing to participate in CNE activities, sponsors have withdrawn their support for these activities, and many activities have been cancelled.

use the ACCME Standards for Commercial Support to ensure the integrity of educational activities provided by jointly accredited organizations. The Joint Accreditation Program, formally launched in 2009, continues to grow. The ACCME Standards of Commercial Support are still used by ANCC and ACPE in the Joint Accreditation Program.

In 2011, ANCC evaluated its accredited organizations' compliance with the Standards for Commercial Support and identified opportunities for clarity and improvement as the standards were interpreted, understood and operationalized within the nursing professional development industry. Based on this information, ANCC developed its Content Integrity Standards for Industry Support in Continuing Nursing Educational Activities (Appendix A). The ANCC Content Integrity Standards are based on the Food and Drug Administration's Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64074 - 64100 (December 3, 1997) (FDA Final Guidance)<sup>4</sup>, and the Department of Health and Human Services Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731-23743 (May 5, 2003). The ANCC Content Integrity Standards were carefully crafted and reviewed by legal counsel on several occasions to ensure compliance with applicable program guidance. ANCC's Content Integrity Standards were then cross-walked with the ACCME Standards for Commercial Support<sup>5</sup> and the PhRMA standards to ensure congruence and equivalence. This was important to facilitate consistent application of commercial support standards across the medical, nursing and pharmaceutical continuing education industries, and to maximize understanding, interpretation and compliance of those who use the standards. Congruence and equivalency also are important to equitable and legally defensible administration of the ANCC/ACCME/ACPE Joint Accreditation Program, which requires consensus of the three accrediting organizations in determining whether to award joint accreditation. The ANCC Content Integrity Standards were then reviewed and approved by ANCC's Commission on Accreditation, the panel of continuing nursing education experts that governs the ANCC Accreditation Program and is responsible for making all accreditation-related decisions.

ANCC published its Content Integrity Standards in January 2012 and the standards went into effect on January 1, 2013. They are entirely congruent with and equivalent to the ACCME Standards for Commercial Support. The most recent cross-walk between the ANCC Content Integrity Standards and the ACCME Standards for Commercial Support (Appendix B) demonstrates the congruence and equivalency of the standards. ANCC's standards have been well-received by the nursing professional development community. Understanding of both the spirit and letter of the requirements has improved. Compliance has increased. Integrity in the educational activities provided has been enhanced.<sup>6</sup>

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<sup>4</sup> ACCME's Standards for Commercial Support also are based on the FDA Final Guidance.

<sup>5</sup> ANCC's Content Integrity Standards have been cross-walked against each revision of the ACCME Standards for Commercial Support.

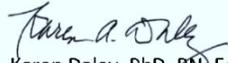
<sup>6</sup> These phenomena may result from the translation of the language in the ACCME Standards for Commercial Support (which were geared toward the medical profession) into language commonly understood and accepted within the continuing nursing education industry and nursing profession, as well as the additional detail and guidance on particular operational issues of concern to CNE providers. For example, Section F of ANCC's Content Integrity Standards provides more detailed guidance to assist accredited providers to determine whether conflicts of interest exist and how they must be resolved. Section G of ANCC's Content Integrity Standards prohibits recruitment of learners by sponsors. Section H of ANCC's Content Integrity Standards provides added clarity around separation of promotional activities from educational activities. Section I of ANCC's Content Integrity Standards addresses promotional giveaways at CNE activities. These improvements were made in response to trending concerns raised by accredited providers of continuing nursing education activities when the ACCME Standards for Commercial Support were in effect.

ANA's and ANCC's historic and ongoing efforts to ensure integrity in continuing education for nurses, including the development of ANCC's Content Integrity Standards, warrant ANCC's inclusion in the list of accreditors. This action is necessary to avoid the disparate impact of this rule on nursing professional development and to sustain and expand a competent nursing workforce to meet our nation's health needs.

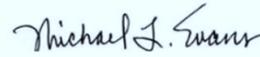
For these reasons, ANA and ANCC urgently request that CMS amend 42 CFR 403.904(g) by adding the American Nurses Credentialing Center to the list of accreditors exempt from reporting requirements. By doing so, CMS will remove the barriers to nursing education and practice unintentionally created by implementation of the Physician Payment Sunshine Act.

Thank you for your consideration of this request. Please direct any questions or follow up to Maureen Cones, Associate General Counsel, at [Maureen.Cones@ana.org](mailto:Maureen.Cones@ana.org) or 301-628-5123.

Sincerely,



Karen Daley, PhD, RN, FAAN  
President  
American Nurses Association



Michael Evans, PhD, RN, NEA-BC, FAAN  
President  
American Nurses Credentialing Center

cc: Elisabeth Handley, Acting Director of Program Integrity, CMS  
Marla Weston, Chief Executive Officer, ANA